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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,499	07/07/2005	Hisakazu Hojo	050412	2008

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EXAMINER	
BEKKER, KELLY JO	

ART UNIT	PAPER NUMBER
1781	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,499	HOJO ET AL.	
	Examiner	Art Unit	
	KELLY BEKKER	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7 and 9-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 5-7, and 9-12 remain pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 22, 2010 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5-7, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luhadiya et al (US 6,811,800 B2) as evidenced by Mallangi et al (US 6,039,986).

Luhadiya et al (Luhadiya) teaches of a food additive by teaching of a calcium fortified protein containing beverage which can be easily incorporated into other food or beverage products (abstract). Luhadiya teaches that the fortified beverage, which is the food additive, may be mammals milk or a soymilk, which inherently contains soybean which is an ingredient derived from vegetables (which are defined in the dictionary as the edible part of a plant) (abstract, column 3 lines 47-50, examples 5 and 7 and claims 4, 12, 14, 25, 26). Luhadiya teaches that the food additive composition comprises a variety of embodiments in mammalian milk, including up to 3100ppm additional soluble calcium, about 0.002-2.5% of an added stabilizer, and 0-0.5% of a chelating agent (column 4 lines 60-67); up to 2500ppm additional soluble calcium, about 0.002-1% added stabilizer, and about 0-0.35% chelating agent (Column 5 lines 1-6); and up to 2200ppm additional soluble calcium, about 0.005-0.5% added stabilizer, and about 0-

0.15% chelating agent (Column 5 lines 6-12); Thus encompassing an embodiment (with 2200ppm additional calcium) of an additive comprising 100 parts of at least one organic soluble calcium compound, 2.27-227 parts stabilizer, and 0-68 parts of a chelating agent. Luhadiya teaches that the food additive composition comprises a variety of embodiments in plant/vegetable derived milk, including up to 4500ppm additional soluble calcium, about 0-2.5% stabilizer, and about 0.01-1% chelating agent (Column 5 lines 41-47); up to 2500ppm additional soluble calcium, about 0-1% stabilizer, and about 0.04-0.7% chelating agent (Column 5 lines 47-54); and up to 2100ppm additional soluble calcium, about 0-0.5% stabilizer, and about 0.08-0.5% chelating agent (Column 5 lines 54-60); Thus encompassing an embodiment (with 2100ppm additional calcium) of an additive with a vegetable derived component, 100 parts of at least one organic soluble calcium compound, 0-555.5 parts of a stabilizer, and 2.2-222 parts of a chelating agent. It is noted that the teachings of Luhadiya are more broad than the instantly claimed part ratios, however, the teachings of Luhadiya clearly encompass the claimed part ratios and the determination of a known ingredient within a known range would have been obvious and routine determination to one of ordinary skill in the art. Luhadiya teaches that the stabilizers include gum arabic, polysaccharides, gum ghatti, xanthan gum, and locust bean gum (Column 5 line 61 through Column 6 line 8). It is noted that the teachings of Luhadiya are more broad than the instantly claimed stabilizer of gum arabic as recited in claim 1, and stabilizer gum arabic with an emulsifier or other additive as recited in claim 2, and stabilizer gum arabic and specific additional component as recited in claims 6 and 7, however, the teachings of Luhadiya clearly encompass the claimed stabilizer and stabilizer/additive compositions, and the selection of a known stabilizer/additive for optimization of stability would have been obvious and routine determination to one of ordinary skill in the art. Luhadiya teaches that the chelating agents include free organic acids and their alkali metal salts, including sodium citrate (Column 6 lines 17-33). Luhadiya teaches that the teaches that the additive calcium, which is at least one organic compound, is calcium carbonate (Column 8 lines 40-44). Specifically regarding the solubility of the inorganic compound, as Luhadiya teaches of the same organic calcium compound disclosed and claimed (claim

3), calcium carbonate, one of ordinary skill in the art would expect that the compound of Luhadiya inherently have the same solubility as the inorganic compound instantly claimed.

Luhadiya does not specifically teach the calcium ion concentration as greater than or equal to zero and less than or equal to ten, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion as recited in claims 1 and 2, and to the food composition to which the additive is combined as coffee or black tea as recited in claim 11.

Regarding the calcium ion concentration as greater than or equal to zero and less than or equal to ten, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion, it would have been obvious to one of ordinary skill in the art for the calcium enriched milk additive as taught by Luhadiya to contain as low as an amount as possible, including as low as 0%, calcium ions, in order to ensure that there were no free calcium ions to destabilize the milk proteins in the additive composition; to do so would be obvious to one of ordinary skill in the art as it was well known in the art, as evidenced by Mallangi, for protein destabilization, e.g. coagulation and precipitation, in materials, such as milk, to be mainly attributed to free calcium ions in the system (Column 1 lines 26-33). Specifically regarding the method in which the calcium ion concentration is obtained, as the instant claims are directed towards products (not methods), and as both products (the instantly claimed product and the product which is obvious over the prior art) have the same calcium ion resultant concentration, one of ordinary skill in the art would not expect that the method of obtaining such a calcium ion concentration to patentably distinguish the instantly claimed products.

Regarding the food composition to which the additive is combined as coffee or black tea, as Luhadiya teaches of a food additive which is milk and which can be easily incorporated into other beverage products, the formation of a food composition which is coffee or black tea with the food additive would have been obvious and within the routine determination of one of ordinary skill in the art. The food composition of coffee

or black tea would have been obvious because Luhadiya teaches of a nutrient enhanced milk additive and milk was known to be added to coffee and black tea, and thus the use of such a milk additive in a known means would have been routine determination to produce the final product desired.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Luhadiya et al (US 6,811,800 B2) as evidenced by Mallangi et al (US 6,039,986), further in view of Hojo et al (US 6,254,905 B1).

Luhadiya teaches of a food additive by teaching of a calcium fortified protein containing beverage, including calcium carbonate which is an inorganic compound component, which can be easily incorporated into other food or beverage products, as discussed above.

Luhadiya is silent to the weight average particle diameter of the inorganic compound component as greater than of equal to 0.04um and less than or equal to 0.8um as recited in claim 9.

Hojo et al (Hojo) teaches of a food additive composition for enhancing the calcium content of foods, including milks, and containing an organic compound calcium carbonate (abstract and column 1 lines 9-15). Hojo teaches that if the weight average diameter of the calcium component is greater than 0.8um, the calcium agent is easy to precipitate so that the composition can not be used for foods being stored for a long period of time (Column 9 lines 17-23). Hojo teaches that the particle size is preferably greater than or equal to 0.04um and less than or equal to 0.8um for the purpose of fairly long storage stability (Column 9 lines 7-23).

Regarding the weight average particle diameter of the inorganic compound component as greater than of equal to 0.04um and less than or equal to 0.8um, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the inorganic, calcium carbonate component as taught by Luhadiya to have a weight average particle diameter of greater than of equal to 0.04um and less than or equal to 0.8um for the purpose of fairly long storage stability as taught by Hojo.

Alternatively, claims 1-3, 5-7, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luhadiya et al (US 6,811,800 B2) as evidenced by Mallangi et al (US 6,039,986) and in view of Hojo et al (US 6,254,905 B1).

Luhadiya et al (Luhadiya) teaches of a food additive by teaching of a calcium fortified protein containing beverage which can be easily incorporated into other food or beverage products (abstract). Luhadiya teaches that the fortified beverage, which is the food additive, may be mammals milk or a soymilk, which inherently contains soybean which is an ingredient derived from vegetables (which are defined in the dictionary as the edible part of a plant) (abstract, column 3 lines 47-50, examples 5 and 7 and claims 4, 12, 14, 25, 26). Luhadiya teaches that the food additive composition comprises a variety of embodiments in mammalian milk, including up to 3100ppm additional soluble calcium, about 0.002-2.5% of an added stabilizer, and 0-0.5% of a chelating agent (column 4 lines 60-67); up to 2500ppm additional soluble calcium, about 0.002-1% added stabilizer, and about 0-0.35% chelating agent (Column 5 lines 1-6); and up to 2200ppm additional soluble calcium, about 0.005-0.5% added stabilizer, and about 0-0.15% chelating agent (Column 5 lines 6-12); Thus encompassing an embodiment (with 2200ppm additional calcium) of an additive comprising 100 parts of at least one organic soluble calcium compound, 2.27-227 parts stabilizer, and 0-68 parts of a chelating agent. Luhadiya teaches that the food additive composition comprises a variety of embodiments in plant/vegetable derived milk, including up to 4500ppm additional soluble calcium, about 0-2.5% stabilizer, and about 0.01-1% chelating agent (Column 5 lines 41-47); up to 2500ppm additional soluble calcium, about 0-1% stabilizer, and about 0.04-0.7% chelating agent (Column 5 lines 47-54); and up to 2100ppm additional soluble calcium, about 0-0.5% stabilizer, and about 0.08-0.5% chelating agent (Column 5 lines 54-60); Thus encompassing an embodiment (with 2100ppm additional calcium) of an additive with a vegetable derived component, 100 parts of at least one organic soluble calcium compound, 0-555.5 parts of a stabilizer, and 2.2-222 parts of a chelating agent. It is noted that the teachings of Luhadiya are more broad than the instantly claimed part ratios, however, the teachings of Luhadiya clearly encompass the claimed part ratios and the determination of a known ingredient within a known range

would have been obvious and routine determination to one of ordinary skill in the art. Luhadiya teaches that the stabilizers include gum arabic, polysaccharides, gum ghatti, xanthan gum, and locust bean gum (Column 5 line 61 through Column 6 line 8). Luhadiya teaches that the chelating agents include free organic acids and their alkali metal salts, including sodium citrate (Column 6 lines 17-33). Luhadiya teaches that the additive calcium, which is at least one organic compound, is calcium carbonate (Column 8 lines 40-44). Specifically regarding the solubility of the inorganic compound, as Luhadiya teaches of the same organic calcium compound disclosed and claimed (claim 3), calcium carbonate, one of ordinary skill in the art would expect that the compound of Luhadiya inherently have the same solubility as the inorganic compound instantly claimed.

Luhadiya does not specifically teach the calcium ion concentration as greater than or equal to zero and less than or equal to ten, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion as recited in claims 1 and 2, to the food composition to which the additive is combined as coffee or black tea as recited in claim 11, and to the weight average particle diameter of the inorganic compound component as greater than of equal to 0.04um and less than or equal to 0.8um as recited in claim 9.

Hojo et al (Hojo) teaches of a food additive composition for enhancing the calcium content of foods, including milks, and containing an organic compound calcium carbonate (abstract and column 1 lines 9-15). Hojo teaches that if the weight average diameter of the calcium component is greater than 0.8um, the calcium agent is easy to precipitate so that the composition can not be used for foods being stored for a long period of time (Column 9 lines 17-23). Hojo teaches that the particle size is preferably greater than or equal to 0.04um and less than or equal to 0.8um for the purpose of fairly long storage stability (Column 9 lines 7-23). Hojo teaches that when the additive is added to cows milk and a super high temperature sterilization is applied, the stability with passage of time of the calcium agent becomes poor because of an insufficient heat resistance of gum arabic, and accordingly, the preferable composition for producing a food additive with long life is a composition wherein per 100 parts of the calcium, 1-60

parts of gum arabic, and 1-60 pars of another additive are used, wherein gum arabic is not less than 20% of the weight of itself and the other additive. Hojo teaches that the other additive may include sucrose fatty acid esters having a hydrophilic-lipophilic balance of not less than 8, polyglycerol fatty acid esters and polysaccharide which may include tamarind gum, gum ghatti, traganth gum, xanthan gum, pullulan, cassia gum, locust bean gum, arabinogalactan, and sclero gum. Hojo teaches that in order to enhance the heat resistance the additive is more preferably at least one seleced from a sucrose fatty acid ester having an HLB value of not less than 8, PGA, tamarind gum, gum ghatti, xanthan gum, pullulan, locust bean gum, arabinogalactan and sclero gum. Refer specifically to Column 6 lines 58-64 and Column 7 lines 25-65. Hojo teaches that 1-60 parts gum arabic is essntial to the stable food additive composition, by teaching that it is included in all embodiments of the invention (all).

Regarding the food additive as specifically containing 1-90 parts gum arabic as recited in claims 1 and 2, and 1-90 parts of at least one additive D selected from the group consisting of emulsifiers, thickening stabilizers, modified starches, soybean polysaccharides and oligosaccharides as recited in claim 2, wherein D is at least one selected from the group consisting of sucrose fatty acid esters having a hydrophilic-lipophilic balance of not less than 8, glycerol fatty acid esters, sorbitan fatty acid esters, propylene glycol fatty acid esters, modified starches, soybean polysaccharides, propylene glycol alginic acid esters, tamarind gum, gum ghatti, traganth gum, xanthan gum, pullulan, cassia gum, locust bean gum, arabinogalactan, sclero gum, and origosaccharides as recited in claims 6 and 7, wherein the gum arabic is not less than 20% of the total weight of itself and additive D as recited in claim 2, as stated above, it is noted that the teachings of Luhadiya are more broad than the instantly claimed stabilizer of gum arabic as recited in claim 1, and stabilizer gum arabic with an emulsifier or other additive as recited in claim 2, and stabilizer gum arabic and specific additional component as recited in claims 6 and 7, however, the teachings of Luhadiya clearly encompass the claimed stabilizer and stabilizer/additive compositions, and the selection of a known stabilizer/additive for optimization of stability would have been obvious and routine determination to one of ordinary skill in the art. Alternatively, it

would have been obvious to one of ordinary skill in the art for the 2.27-227 parts stabilizer (in the mammalian based composition) or 0-555.5 parts stabilizer (in the plant based composition) to comprise 1-60 parts gum arabic and 1-60 parts of an additional stabilizer, more preferably at least one selected from a sucrose fatty acid ester having an HLB value of not less than 8, PGA, tamarind gum, gum ghatti, xanthan gum, pullulan, locust bean gum, arabinogalactan and sclero gum, wherein the gum arabic comprises at least 20% weight of itself and the other additive, in view of Hojo. One of ordinary skill in the art would have been motivated to use 1-60 parts of the component D stabilizer as the additive in order to form a more heat stable composition as taught by Hojo; one of ordinary skill in the art would have been motivated to use 1-60 parts gum arabic, wherein gum arabic comprises at least 20% by weight of itself and the other stabilizer additive, as the main stabilizer as Luhadiya teaches that gum arabic is a stabilizer for a milk calcium enrichment food additive, and as Hojo teaches that 1-60 parts gum arabic, included in a weight of at least 20% itself and other stabilizers, is essential to a stable calcium enrichment food additive for foods, including milks.

Regarding the calcium ion concentration as greater than or equal to zero and less than or equal to ten, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion, it would have been obvious to one of ordinary skill in the art for the calcium enriched milk additive as taught by Luhadiya to contain as low as an amount as possible, including as low as 0%, calcium ions, in order to ensure that there were no free calcium ions to destabilize the milk proteins in the additive composition; to do so would be obvious to one of ordinary skill in the art as it was well known in the art, as evidenced by Mallangi, for protein destabilization, e.g. coagulation and precipitation, in materials, such as milk, to be mainly attributed to free calcium ions in the system (Column 1 lines 26-33). Specifically regarding the method in which the calcium ion concentration is obtained, as the instant claims are directed towards products (not methods), and as both products (the instantly claimed product and the product which is obvious over the prior art) have the same calcium ion resultant concentration, one of

ordinary skill in the art would not expect that the method of obtaining such a calcium ion concentration to patentably distinguish the instantly claimed products.

Regarding the food composition to which the additive is combined as coffee or black tea, as Luhadiya teaches of a food additive which is milk and which can be easily incorporated into other beverage products, the formation of a food composition which is coffee or black tea with the food additive would have been obvious and within the routine determination of one of ordinary skill in the art. The food composition of coffee or black tea would have been obvious because Luhadiya teaches of a nutrient enhanced milk additive and milk was known to be added to coffee and black tea, and thus the use of such a milk additive in a known means would have been routine determination to produce the final product desired.

Regarding the weight average particle diameter of the inorganic compound component as greater than of equal to 0.04um and less than or equal to 0.8um, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the inorganic, calcium carbonate component as taught by Luhadiya to have a weight average particle diameter of greater than of equal to 0.04um and less than or equal to 0.8um for the purpose of fairly long storage stability as taught by Hojo.

Claims 1-3, 5-7, and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hojo et al. (US 6254905 B1) in view of the combination of Koumarianos (US 6488957) and Grossman (About.com, “Facts About Iron” pages 1-5 http://ibdcrohns.about.com/cs/nutrition/a/fdairon.html) and Klahorst (“Calcium, An Important Nutrient” pages 1-5 http:www.ifanca.og/newsletter/2001_05.htm) and Fennema (Food Chemistry, 2nd Edition, pages 778 and 779).

Hojo et al. (Hojo) teaches of a food additive composition which contains 100 parts by weight of calcium carbonate, i.e. a hardly water soluble inorganic compound with a solubility in water at 20C of not more than 0.1g/100g of water (Column 3 lines 50-58), 1-60 parts gum arabic (Column 3 lines 50-58) and an additive including the stabilizer sucrose fatty acid esters having a hydrophilic-lipophilic balance of not less than 8, wherein the gum arabic is not less than 20% by weight of the gum arabic and

sucrose fatty acid esters combined (Column 4 lines 1-8). Hojo teaches that the composition contains 1-60 parts gum arabic and stabilizers total, wherein the gum arabic comprises most preferably about 55-100% of the composition, thus the stabilizer additive is included at 0-27 parts (0-45% of the 1-60 parts) and the gum arabic is included at 0.55-60 parts (55-100% of the 1-60 parts) in the composition as taught by Hojo. Hojo teaches that the food additive may contain ferrous gluconate or sodium iron citrate i.e. a gluconate or citrate chelating agent as instantly claimed (Column 11 lines 4-8). Hojo teaches that the inorganic compound, i.e. the calcium agent, has a particle size of 0.8um or less and 0.04um or more (Column 9 lines 7-26). Hojo teaches that the food additive may be used, and thus contained in black tea or coffee (Column 10 line 66 through Column 11 line 3). Hojo teaches that the additive composition includes gum arabic and locust bean gum, which are derived from vegetables. Furthermore, it would have been obvious for the food additive to include a component that was derived from vegetables so that the final product would contain the known benefits, such as nutritional benefits, from vegetables. Hojo teaches that the calcium ion concentration is greater than ten and less than or equal to 500, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion (Column 8 lines 23-33).

Hojo is silent to the amount of the ferrous gluconate, sodium iron citrate or chelating agent in the additive composition, and to the calcium ion concentration as 0 to less than 10% as recited in claims 1 and 2.

Koumarianos teaches of a food additive composition (abstract). Koumarianos teaches that the food additive composition contains minerals, including iron and that the amount of the mineral in the food additive composition is determined based on the recommended daily dosage (Column 5 lines 8-17).

Grossman teaches that the recommended daily amount of iron in 2001 for males ranged from 8-11mg per day and for females 8-18 mg per day. (page 3)

Klahorst, page 2, teaches that the recommended daily amount of calcium in 2001 was 1000-1300 mg per day.

Fennema teaches the problem of metal ion stability was known to be specifically addressed with the use of chelating agents, including citric acid and its derivatives, which react with metallic ions to form stable complexes in foods (pages 778-779).

Regarding the amount of the ferrous gluconate and sodium iron citrate or chelating agent in the additive composition as recited in claims 1 and 2, ferrous gluconate and sodium iron citrate were known food supplements that were sources of iron. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an amount of the ferrous gluconate and/or sodium iron citrate and thus an amount of chelating agent in the additive composition depending on the recommended daily amounts of iron and the amount of iron desired in the final composition as taught by Koumarianos. It would have been further obvious to one of ordinary skill in the art at the time the invention was made for the vitamins and minerals in the food additive, including calcium and iron, to be included in the full recommended daily amounts so that when consuming the food additive the consumers would not be required to take other additives to obtain complete daily fulfillment of the said vitamins and minerals. Thus, one would have been further motivated to include an amount of iron to calcium in the nutritional additive composition based upon the recommended daily amounts of iron and calcium, so that the nutritional additive would fulfill the requirements for both minerals simultaneously; and as the RDA of calcium: iron was 1300:8 or 100:0.6 to 1000:18 or 100:1.8 as taught by Grossman and Klahorst, at the time the invention was made, one would have been motivated to include 0.6-1.8 parts of ferrous gluconate and/or sodium iron citrate, i.e. an iron source, per 100 parts of calcium carbonate, i.e. a calcium source. Thus, the composition as taught by Hojo would comprise 0.6-1.8 parts of ferrous gluconate and/or sodium iron citrate which are chelating agents as instantly claimed.

Regarding the calcium ion concentration as 0% or greater to less than 10%, Hojo (Column 8 lines 34-43) teaches that the calcium ion concentration is balanced for stability and preventing damage of the proteins and gelling of the food composition. Hojo teaches that too little can cause instability and that too much can cause damage to the food proteins and gelling. Hojo teaches that the calcium ion concentration as about

10-500, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to decrease the calcium ion concentration at or below 10 if at levels at and below 10 were stable, in order to ensure that protein destruction and gelling of the food composition was prevented (as Hojo teaches that such destruction and gelling is caused by high calcium ion concentrations). To balance a known composition based on known effects and needs would have been obvious and routine determination of one of ordinary skill in the art at the time the invention was made. Furthermore, the only reason Hojo teaches a minimum calcium ion concentration of 10 is because of the calcium agent instability; and as the problem of metal ion stability was known to be specifically addressed with the use of chelating agents, including citric acid and its derivatives, which react with metallic ions to form stable complexes in foods, the decrease of the calcium ion concentration below 10 in order to prevent damage to the proteins and gelling of the food composition as taught by Hojo, wherein the calcium ion agent was stabilized through the use of a chelating agent, as was well known in the art, as taught by Fennema, would have been obvious and within the routine determination to one of ordinary skill in the art. To use a chelating agent and to determine an appropriate amount and type of a known chelating agent would have been further obvious and routine determination to one of ordinary skill in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-7, and 9-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 10, and 11 of U.S. Patent No.6,254,905 B1 ('905). Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a food additive comprising 100 parts of a calcium agent, including calcium carbonate, which is a hardly water soluble inorganic compound with a solubility in water at 20C of not more than 0.1g/100g of water and 1-60 parts gum arabic and additive total, wherein the gum arabic comprises at least 20%, most preferably about 55-99.99% of the composition, and the additive is selected from the same group of ingredients, including vegetable derived components; the additive as included at about 0-27 parts (0-44.11% of the 1-60 parts) and the gum arabic as included at about 0.55-60 parts (55-99.99% of the 1-60 parts) in the composition; a calcium ion concentration wherein the calcium ion concentration of the food additive is obtained by adjusting a solid concentration of the food additive to 10% by weight after pulverization and/or dispersion; the calcium ion weight average diameter particle size distribution as greater than or equal to 0.04um and less than or equal to 0.8um; and a food product which contains the food additive.

The only difference is ‘905 does not claim the addition of 0.01-5 parts of a chelating agent selected from the group consisting of condensed phosphates, malates, succinates, tartarates, glutamates, EDTA salts, and citrates as recited in claims 1 and 2, preferably wherein the chelating agent is one selected from the group consisting of malates, succinates, tartarates, glutamates, EDTA salts, and citrates as recited in claim 5, to the calcium ion concentration as greater or equal to zero and less than or equal to 10 as recited in claims 1 and 2, and to the food additive for coffee or black tea.

In considering obvious variations of the claims for an obvious type double patenting rejection, the pertinent disclosure must be considered (MPEP 804). In the instant case, the pertinent disclosure of ‘905 in regards to the instantly claimed calcium ion concentration (claims 1 and 2 of ‘905) includes column 8 lines 23-42 of the disclosure, in which '905 states that if the calcium ion concentration is less than 10, then the surface stability of the calcium agent is unstable and if the calcium ion concentration is higher, the product tends to increase in viscosity due to the stability of the protein being damaged, and in a worst case, it occasionally gels; the pertinent disclosure of ‘905 in regards to the final food product (claims 10 and 11 of ‘905) includes column 10 line 66 through column 11 line 3, in which '905 states that the food additive can be used for liquid foods including beverages such as cream, coffee, black tea, etc.

Fennema teaches the problem of metal ion stability was known to be specifically addressed with the use of chelating agents, including citric acid and its derivatives, which react with metallic ions to form stable complexes in foods (pages 778-779).

Regarding the addition of 0.01-5 parts of a chelating agent selected from the group consisting of condensed phosphates, malates, succinates, tartarates, glutamates, EDTA salts, and citrates, preferably wherein the chelating agent is one selected from the group consisting of malates, succinates, tartarates, glutamates, EDTA salts, and citrates and the calcium ion concentration as greater or equal to zero and less than or equal to 10, in considering the claims and relevant disclosure of ‘905, it would have been obvious to one of ordinary skill in the art at the time the invention was made to decrease the calcium ion concentration at or below 10 if at levels at and below 10 were stable, in order to ensure that protein destruction and gelling of the food composition

were prevented (as '905 establishes that such destruction and gelling is caused by high calcium ion concentrations). To balance a known composition based on known effects and needs would have been obvious and routine determination of one of ordinary skill in the art at the time the invention was made. Furthermore, the only reason '905 gives a minimum calcium ion concentration of 10 is because of the calcium agent instability; and as the problem of metal ion stability was known to be specifically addressed with the use of chelating agents, including citric acid and its derivatives, which react with metallic ions to form stable complexes in foods (as taught by Fennema), the decrease of the calcium ion concentration below 10 in order to prevent damage to the proteins and gelling of the food composition as stated by '905, wherein the calcium ion agent was stabilized through the use of a chelating agent, as was well known in the art, as taught by Fennema, would have been obvious and within the routine determination to one of ordinary skill in the art. To use a chelating agent and to determine an appropriate amount and type of a known chelating agent would have been further obvious and routine determination to one of ordinary skill in the art through routine experimentation with a result effective variable.

Regarding the food additive for coffee or black tea, the use of the food additive would have been obvious as '905 claims the use of the food additive in foods, which as based on the relevant disclosure, encompasses beverages, such as coffee and black tea. Furthermore, the use of an additive in a known means would have been routine determination to produce the final product desired.

Response to Arguments

Applicant's arguments and declaration filed September 22, 2010 have been fully considered but they are not persuasive.

Applicant argues that the references do not teach the calcium ion concentration as 0-10 and that Hojo specifically teaches away from such an embodiment as Hojo teaches that a calcium ion of less than 10 causes unstable ions. Applicant's argument is not convincing as Hojo (Column 8 lines 34-43) teaches that the calcium ion concentration is balanced for *stability and preventing damage of the proteins and gelling*

of the food composition; Hojo teaches that too little can cause instability and that too much can cause damage to the food proteins and gelling; Hojo teaches that the calcium ion concentration as about 10-500, wherein the calcium ion concentration is obtained by adjusting a solid matter concentration of calcium to 10% by weight after pulverization and/or dispersion. Thus, as previously stated, it would have been obvious to one of ordinary skill in the art at the time the invention was made to decrease the calcium ion concentration at or below 10 if at levels at and below 10 the composition was stable and in order to ensure that protein destruction and gelling of the food composition was prevented. To balance a known composition based on known effects and needs would have been obvious and routine determination of one of ordinary skill in the art at the time the invention was made. Furthermore, the only reason Hojo teaches a minimum calcium ion concentration of 10 is because of the calcium agent instability; and as the problem of metal ion stability was known to be specifically addressed with the use of chelating agents, including citric acid and its derivatives, which react with metallic ions to form stable complexes in foods, the decrease of the calcium ion concentration below 10 in order to prevent damage to the proteins and gelling of the food composition as taught by Hojo, wherein the calcium ion agent was stabilized through the use of a chelating agent, as was well known in the art, as taught by Fennema, would have been obvious and within the routine determination to one of ordinary skill in the art. To use a chelating agent and to determine an appropriate amount and type of a known chelating agent would have been further obvious and routine determination to one of ordinary skill in the art.

Applicant argues in the remarks and declaration that there is a difference between a food additive composition not containing a chelating agent as discussed by Hojo et al and a food additive composition containing a chelating agent as disclosed by the present invention. Applicant supports this argument with data of a food additive and a food additive used to prepare a calcium enriched whiteners. Applicant's argument is not convincing as:

- Although Hojo teaches of embodiments without chelating agents, Hojo also discloses embodiments with chelating agents, such as citrates and

gluconates (Column 11 lines 3-8); thus although applicant has shown embodiments of Hojo which are different from the instantly claimed invention, applicant has not compared the closest prior art, i.e. the embodiments of Hojo with chelating agents;

- The instantly claimed composition with chelating agents would have been obvious to one of ordinary skill in the art as discussed above;
- It is not surprising or unexpected that there is a difference between a food additive composition that contains calcium ions wherein a chelating agent is and is not included; as taught by Fennema, chelating agents were known to stabilize metal ions, and the action of such a component would have been obvious and expected to one of ordinary skill in the art; and
- Additionally, it is noted that the evidence has ratings, such as 1, 4, and 5, but no scale of possible ranges has been given; For example it is unclear as to if the scale is 1-5 or 1-10 or 1-1000, etc.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KELLY BEKKER whose telephone number is (571)272-2739. The examiner can normally be reached on Monday through Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kelly Bekker/
Examiner
Art Unit 1781